

2017 MAY 23 AM 8:48
U.S. DISTRICT COURT
EASTERN DISTRICT
OF NEW YORK

FILED
CLERK

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

----- X
ABBOTT LABORATORIES, ABBOTT :
DIABETES CARE INC., and ABBOTT DIABETES :
CARE SALES CORPORATION, :
:

Plaintiffs, :

-against- :

H&H WHOLESALE SERVICES, INC., HOWARD :
GOLDMAN, DAVID GULAS, and JOHN DOES 1- :
10, :

Defendants. :
----- X

17 Civ. _____

COMPLAINT

JURY TRIAL DEMANDED

**FILED UNDER SEAL
PURSUANT TO 15 U.S.C. § 1116**

CV 17 - 3095 

Plaintiffs Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corporation (collectively, “Abbott”), by and through their attorneys, Patterson Belknap Webb & Tyler LLP, for their Complaint against Defendants H&H Wholesale Services, Inc. (“H&H”), Howard Goldman, and David Gulas (collectively, the “H&H Defendants”), and John Does 1-10, allege as follows:

NATURE AND OVERVIEW OF THE ACTION

1. In this anti-counterfeiting action, Abbott seeks to prevent the H&H Defendants from trafficking repackaged Abbott international diabetic test strips in counterfeit U.S. retail packaging. The H&H Defendants are trafficking these counterfeit Abbott products in an attempt to subvert an injunction entered by this Court in a related action, which prohibits them from buying or selling international FreeStyle-brand diabetic test strips in the United States. That injunction was intended to shut down the H&H Defendants’ fraudulent scheme to pass off international FreeStyle strips to U.S. consumers and insurers, bilking Abbott and the insurers out of millions of dollars in the process. But despite being bound by the ongoing injunction, the

H&H Defendants have escalated from unlawful gray-market diversion of international test strips to outright criminal counterfeiting, and are now selling international test strips that have been removed from their international packaging and put into counterfeit U.S. retail packaging.

2. Abbott sells medical equipment for diabetic patients, including the well-known FreeStyle® and FreeStyle Lite® blood glucose test strips (collectively, “FreeStyle test strips”), which are used by diabetics to monitor their blood glucose levels. Millions of individuals with diabetes use FreeStyle test strips on a daily basis to monitor their blood sugar and help them control their disease.

3. In a related action, *Abbott Laboratories et al. v. Adelpia Supply USA et al.*, No. 1:15-cv-05826 (E.D.N.Y.) (the “Related Action”) Abbott sued H&H and Howard Goldman, among other defendants, alleging causes of action in connection with H&H and Howard Goldman’s purchase and sale of international FreeStyle test strips that had been diverted into the United States. The packaging and instructional inserts of international FreeStyle test strips differ from the packaging and instructional inserts of U.S. retail FreeStyle test strips in many ways, and (among other issues) as a result the international packaging and instructional inserts do not comply with FDA requirements. *See* Related Action Dkt. No. 131.

4. In the Related Action, this Court entered first a Temporary Restraining Order and then a Preliminary Injunction prohibiting, among other things, H&H and Howard Goldman from purchasing or selling international FreeStyle test strips in the United States. *See* Related Action Dkt. Nos. 19, 21, 131, 131-1.

5. As stated in the Order in the Related Action granting the Preliminary Injunction, this Court found Abbott likely to succeed on its trademark claims because there are material differences in the packaging and instructional inserts of U.S. retail and international FreeStyle

test strips; because the packaging and instructional inserts of international FreeStyle test strips are likely to confuse U.S. consumers; and because the diversion of international FreeStyle test strips interferes with Abbott's bona fide quality control efforts. *See* Related Action Dkt. No. 131.

6. As reflected in the same Order in the Related Action, H&H and Howard Goldman, along with other defendants in the Related Action, took part in a scheme to divert lower-priced international FreeStyle test strips into the United States and fraudulently submit them for insurance coverage and rebates by Abbott. Nearly all consumers purchase FreeStyle test strips through insurance, and after insurers pay the dispensing pharmacy, Abbott pays a contractually determined rebate to the insurers. International FreeStyle test strips are not eligible to be paid by insurance in the U.S. (or for the rebate that Abbott pays to insurers), and so the defendants' scheme was to dispense diverted international FreeStyle test strips to consumers, but to fraudulently represent to the insurers that the patient had been dispensed a box of U.S. retail strips. The patients received no benefit from this insurance fraud, because they paid the same copay they would have paid for U.S. retail strips, but received a box of international strips instead. H&H, Howard Goldman, and the other defendants in the Related Action thus enriched themselves at the expense of Abbott, who paid unwarranted rebates to insurers and lost money on each such fraudulent sale, while exposing U.S. consumers to confusing international boxes that are not approved by the FDA and that are unlawful to sell in the United States. *See* Related Action Dkt. No. 131.

7. The Preliminary Injunction issued in the Related Action was intended to shut down this fraudulent scheme by prohibiting the unlawful sale of diverted international FreeStyle test strips in the United States. The Preliminary Injunction issued against H&H and Howard

Goldman in the Related Action was upheld on appeal by the Second Circuit. *Abbott Laboratories v. H&H Wholesale Services, Inc.*, Nos. 15-3785-cv(L), 15-3858-cv(CON), 2016 U.S. App. LEXIS 19768 (2d Cir. Nov. 3, 2016). It remains in effect as of the date of this Complaint, as the Related Action is still in the discovery phase.

8. But Abbott has discovered that the Preliminary Injunction has not shut down the H&H Defendants' fraudulent scheme, because the H&H Defendants have escalated their unlawful activity from gray-market diversion to outright counterfeiting. Having been enjoined by this Court from selling international boxes of FreeStyle test strips, H&H is now selling international FreeStyle test strips that have been removed from their international packaging and re-packaged into counterfeit U.S. packaging.

9. Abbott, through private investigators directed by counsel, has purchased such counterfeit FreeStyle test strips directly from H&H, who represented the counterfeits to be genuine U.S. retail FreeStyle test strips. H&H has delivered such counterfeit FreeStyle test strips to businesses located in the Eastern District of New York. Abbott's internal testing and the testing performed by an outside expert have confirmed that the boxes, instructional inserts, and vial labelling of supposedly U.S. retail FreeStyle test strips purchased from H&H are all counterfeit.

10. In addition to flouting this Court's Preliminary Injunction in the Related Action, the H&H Defendants' trafficking in counterfeit FreeStyle test strips poses potential health and safety risks to diabetic patients who rely on FreeStyle test strips to manage their disease. For example, the FDA-mandated expiration date for FreeStyle test strips appears on the box and the vial labelling, both of which have been discarded and replaced by counterfeit boxes and labelling. The counterfeit repackaging of international FreeStyle test strips also removes such

strips from Abbott's quality control procedures, including the ability to pursue recalls, if necessary. Abbott also has no way of knowing how the strips were handled and stored during the counterfeit repacking process.

11. To put an end to the H&H Defendants' potentially dangerous conduct, and to recover the damages caused by it, Plaintiffs now bring this anti-counterfeiting action for injunctive and monetary relief for trademark infringement in violation of Section 32 of the Lanham Act (15 U.S.C. § 1114), false descriptions and false designations of origin in commerce in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125) and New York General Business Law Section 349, trademark dilution in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125) and New York General Business Law Section 360-1, common law unjust enrichment and unfair competition, common law fraud and fraudulent inducement, and common law aiding and abetting fraud.

PARTIES

12. Plaintiff Abbott Laboratories is a publicly traded global healthcare company organized under the laws of the State of Illinois, with its principal place of business at Abbott Park, Illinois. Abbott Laboratories is engaged in the business of manufacturing and marketing health care products.

13. Plaintiff Abbott Diabetes Care Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at Alameda, California. Abbott Diabetes Care Inc. is a wholly-owned operating subsidiary of Abbott Laboratories. Abbott Diabetes Care Inc. is engaged in the business of developing and selling blood glucose monitoring systems, including blood glucose test strips.

14. Plaintiff Abbott Diabetes Care Sales Corporation is a corporation organized under the laws of the State of Delaware, with its principal place of business at Alameda, California. Abbott Diabetes Care Sales Corporation is a wholly-owned operating subsidiary of Abbott Diabetes Care Inc. and is engaged in the business of marketing and selling blood glucose monitoring systems, including blood glucose test strips, in the United States.

15. Defendant H&H Wholesale Services, Inc. (“H&H”) is, upon information and belief, a corporation organized under the laws of the State of Michigan, with a principal place of business at 1099 Rochester Road, Troy, Michigan 48083.

16. Defendant Howard Goldman is, upon information and belief, the owner of H&H. Howard Goldman resides at 2590 Kent Ridge Court, Bloomfield Hills, Michigan 48301, with a principal place of business at 1099 Rochester Road, Troy, Michigan 48083. Defendant Howard Goldman exercises control over H&H and is a moving, conscious, active force behind H&H’s unlawful conduct.

17. Defendant David Gulas is, upon information and belief, an employee of H&H who is responsible for all of H&H’s purchases of diabetic test strips, and upon information and belief resides in Michigan. Upon information and belief, defendant David Gulas exercises control over H&H and is a moving, conscious, active force behind H&H’s unlawful conduct.

18. John Does 1-10 are other persons or entities involved in the manufacture, marketing, distribution and/or sale of counterfeit test strips bearing the FreeStyle trademarks.

JURISDICTION AND VENUE

19. The Court has subject matter jurisdiction over this action under Section 39 of the Trademark Act of 1946 (the “Lanham Act”), 15 U.S.C. § 1121; 28 U.S.C. §§ 1331, 1332,

1338(a), 1338(b), and 1367; 18 U.S.C. §§ 1964 and 1965; and general principles of ancillary and pendent jurisdiction.

20. The amount of damages at issue exceeds \$75,000, exclusive of interest and costs.

21. The Court has personal jurisdiction over each of the defendants pursuant to FRCP Rule 4(k) and/or NY CPLR §§ 301 and 302. The Court also has personal jurisdiction over each of the defendants because the tortious acts described in this complaint (which occurred in New York, among other places), were conducted and/or directed by each of the defendants.

22. Venue is proper in the Eastern District of New York pursuant to 28 U.S.C. § 1391(b) and (c) in that a substantial part of the events or omissions giving rise to the claim occurred in this district, and one or more of the defendants is subject to personal jurisdiction in this district.

THE FACTS

23. Abbott sells the well-known, high-quality FreeStyle blood glucose monitoring systems, which includes FreeStyle test strips. Abbott markets and sells FreeStyle test strips throughout the world, and is viewed as a dependable source of high-quality and reliable test strips.

24. Diabetes is a group of diseases characterized by high blood glucose levels that result from defects in the body's ability to produce and/or use insulin. According to the American Diabetes Association, diabetes affects more than 25 million Americans. Diabetes is a chronic disease that must be managed closely to avoid the risk of serious illness, complications, and even death.

25. Millions of people who have been diagnosed with diabetes depend on Abbott's FreeStyle test strips every day to monitor their blood sugar to enable them to regulate their diet and medication.

26. Diabetes patients use FreeStyle test strips by first placing a test strip into a compatible FreeStyle meter. The patient then obtains a tiny blood sample from an indicated "test site"—which in the United States is the patient's fingertip, upper arm, or palm—using a lancing device. Next, the patient applies the blood sample to the test strip. The test result, or blood glucose reading, is displayed on the meter's digital screen seconds later. Based on this reading, the patient makes decisions concerning when to take insulin and how to adjust his or her diet to ensure a healthy blood-glucose level.

Abbott's Trademarks

27. Abbott Laboratories and Abbott Diabetes Care Inc. are the owners of a family of U.S. trademarks including, among others, the following trademarks that appear on all packaging for FreeStyle® and FreeStyle Lite® blood glucose test strips (collectively referred to herein as the "FreeStyle Marks").

- Abbott Diabetes Care Inc.'s "FREESTYLE" trademark was registered on the Principal Register of the United States Patent and Trademark Office on July 4, 2006, as U.S. Registration No. 3,111,863, and was recognized by the Patent and Trademark Office ("PTO") as incontestable under 15 U.S.C. § 1065 on June 28, 2012;
- Abbott Diabetes Care Inc.'s "FREESTYLE LITE" trademark was registered on the Principal Register of the United States Patent Office on August 19, 2008, as U.S. Registration No. 3,488,499, and was recognized by the PTO as incontestable under 15 U.S.C. § 1065 on May 31, 2014;




- Abbott Diabetes Care Inc.'s  trademark, which consists of a butterfly with a silver body, black wings, yellow and orange oblong shapes on

the wings with two rows of white spots going around the oblong shapes, and with blue shading, was registered on the Principal Register of the United States Patent Office on September 18, 2012, as U.S. Registration No. 4,210,535;

- Abbott Laboratories' "ABBOTT" trademark was registered on the Principal Register of the United States Patent Office on December 15, 2009, as U.S. Registration No. 3,724,557;
- Abbott Laboratories' "ABBOTT" trademark was registered on the Principal Register of the United States Patent Office on August 31, 2010, as U.S. Registration No. 3,842,268;
- Abbott Laboratories' "ABBOTT" trademark was registered on the Principal Register of the United States Patent Office on August 31, 2010, as U.S. Registration No. 3,842,269;
- Abbott Laboratories' "ABBOTT" trademark was registered on the Principal Register of the United States Patent Office on September 6, 2011, as U.S. Registration No. 4,023,123; and



- Abbott Laboratories'  trademark service mark was registered on the Principal Register of the United States Patent Office on June 6, 1989, as U.S. Registration No. 1,542,129 and was recognized by the PTO as incontestable under 15 U.S.C. § 1065 on January 5, 1996.

28. The sale of FreeStyle test strips has been successful in part due to Abbott's marketing and promotion of the FreeStyle brand throughout the country.

29. Abbott distributes over 600 million FreeStyle test strips every year in the United States alone and has sold billions of FreeStyle test strips for over \$1 billion dollars in the United States over the past five years.

30. The FreeStyle brand is recognized in the United States and throughout the world as a high-quality, reliable blood glucose test strip manufactured and distributed by Abbott. FreeStyle test strips are sold in pharmacies throughout the United States and world.

31. As a result of Abbott's extensive advertising and promotion of FreeStyle test strips in connection with the FreeStyle Marks, Abbott's widespread and long-running sale of

FreeStyle test strips, and the recognition that the FreeStyle Marks have achieved, blood glucose test strips bearing FreeStyle Marks have been and are now recognized by the consuming public in the United States and in the trade as originating from a single source: Abbott.

32. Test strips bearing the FreeStyle Marks have come to be known by the purchasing public throughout the United States and abroad as blood glucose test strips of high quality. As a result, the FreeStyle Marks and the goodwill associated with them are of inestimable value to Abbott.

33. Abbott has used and is currently using the FreeStyle Marks in commerce and in connection with its sale of FreeStyle test strips, and plans to continue such use in the future.

Abbott's Manufacturing and Quality Control

34. FreeStyle test strips are manufactured in Ireland with a specific stock keeping unit ("SKU") and lot number. Each lot is only manufactured for sale in a specific country or region. FreeStyle test strips that are manufactured for sale in the United States are assigned different SKU and lot numbers than FreeStyle test strips manufactured for sale outside the United States.

35. Abbott uses the SKU and lot numbers to track where the test strips are shipped and then to monitor them if any safety or quality issues arise.

36. When a recall is warranted, for example, Abbott notifies the regulatory agencies in the countries that were authorized to receive the affected lot number, informing them of the particular issue and seeking their guidance. Abbott then issues a recall notice, which may include a press release and a website posting. For each affected country, Abbott provides a direct notification to all consignees for the affected lot numbers, including distributors, retailers, and pharmacies, notifying them of the issue with the product and what further action is necessary. Where possible, Abbott also directly notifies consumers and health care professionals whose patients have been using the recalled product.

37. Recall notices are only sent to countries and/or consumers that are authorized to have received the particular SKU or lot number that is the subject of the recall. This helps to minimize consumer confusion and unnecessary market disruption; prevent consumers from becoming desensitized to important recall notices as a result of receiving numerous inapplicable notifications; and ensure that consumers do not unnecessarily dispose of their products in instances in which only a specific SKU or lot number is affected. When FreeStyle test strips are repackaged into counterfeit packaging and, as such, separated from their manufacturing lot numbers, it eliminates Abbott's ability to perform a product recall.

38. The repackaging of FreeStyle test strips into counterfeit packaging, with counterfeit boxes and counterfeit vial labels, destroys the connection between the product, its lot number, and its destined distribution. Thus, if the box is subsequently recalled, a consumer may never be made aware of the recall or quality issues concerning the product in their possession. For this reason, FreeStyle test strips that are repackaged into counterfeit boxes present a serious threat to quality assurance and consumer safety.

39. Abbott devotes a substantial amount of effort and resources to ensure product quality and consumer safety. In addition to the pre-market measures Abbott takes, after FreeStyle test strips are distributed, Abbott continues to monitor the market—receiving consumer inquiries, tracking and investigating complaints and market issues, and performing any necessary field actions, including making targeted recalls and initiating legal proceedings. When Abbott discovers product in the United States that is not suitable or approved for sale, Abbott also promptly notifies relevant federal and local law-enforcement authorities.

40. As part of its ongoing efforts to monitor and preserve the FreeStyle trademarks and the underlying quality they represent, Abbott maintains a customer service hotline to

provide assistance to its customers. Customers can contact customer service with various questions and complaints regarding the glucose test strips that they have purchased. In response to these complaints, the customer service representatives gather information from the customer and sometimes request that the customer return the products in question to Abbott for examination. Once the product is returned to Abbott, it is then analyzed to determine if there is in fact a defect in the product, or if it is a counterfeit product.

Abbott Discovers and Investigates the Distribution of Counterfeit FreeStyle Test Strips

41. After learning that United States Customs and Border Protection had seized a shipment of counterfeit boxes of FreeStyle test strips that had been attempted to be smuggled into the United States declared as “plastic sheeting,” Abbott, through its counsel, arranged for the private investigative agency Arthur L. Krinsky and Associates (“Krinsky”) to use a pharmacy to purchase FreeStyle test strips from H&H on December 27, 2016 and January 3, 2017. These cases were marked with lot number 1600508 and an expiration date of January 31, 2018. The test strips H&H delivered were tested, and the shipper case, cartons, instructional inserts, and vial labels were all found to have been counterfeited. H&H’s sale of these counterfeits was referred to the United States Food and Drug Administration Office of Criminal Investigation and Abbott was told that this would be added to an ongoing criminal investigation of H&H.

42. Abbott became concerned that the criminal investigation was not proceeding quickly enough to protect its valuable trademark rights and the hundreds of thousands of patients in the United States suffering from diabetes that use FreeStyle test strips every day, so from the end of March through May, three private investigative firms—Krinsky, Exiger, LLC (“Exiger”), K2 Intelligence, LLC (“K2 Intelligence”)—were directed to make multiple purchases of cases of test strips from H&H.

43. On March 24, 2017, Krinsky purchased two cases of FreeStyle test strips from H&H through a pharmacy. One of the cases was marked with lot number 1600513 and expiration date of May 2018, and each carton in the case was identical. The other case was marked with lot number 1600516 and an expiration date of May 2018, and each carton in the case was identical. Abbott determined that the product had a counterfeit carton, counterfeit instructional insert, and counterfeit vial label.

44. On April 20, 2017, K2 Intelligence used a nursing home located in the Eastern District of New York to purchase product from H&H. This package contained 24 sealed cartons of FreeStyle test strips. Eleven of the cartons were marked with lot number 1625010 and an expiration date of September 30, 2018. Abbott determined that the eleven cartons were marked with lot number 1625010 had counterfeit cartons, counterfeit instructional inserts, and counterfeit vial labels.

45. On April 21, 2017, K2 Intelligence purchased a carton of FreeStyle test strips marked with lot number 1625010 and expiration date of September 30, 2018 from Health Point Drugs in Brooklyn, New York. This pharmacy had previously purchased diverted international boxes of FreeStyle test strips from H&H. The investigators purchased whatever box the pharmacist handed to the investigator. Abbott determined that the product had a counterfeit carton, counterfeit instructional insert, and counterfeit vial label.

46. On April 21, 2017, K2 Intelligence purchased a carton of FreeStyle test strips marked with lot number 1623015 and an expiration date of September 30, 2018 from Nevins Drugs Inc. in Brooklyn, New York. This pharmacy had previously purchased diverted international boxes of FreeStyle test strips from H&H. The investigators purchased whatever box

the pharmacist handed to the investigator. Abbott determined that the product had a counterfeit carton, counterfeit instructional insert, and counterfeit vial label.

47. On April 21, 2017, K2 Intelligence purchased a carton of FreeStyle test strips marked with lot number 1600508 and an expiration date of January 2018 from Prospect Drugs in Brooklyn, New York. This pharmacy had previously purchased diverted international boxes of FreeStyle test strips from H&H. The investigators purchased whatever box the pharmacist handed to the investigator. Abbott determined that the product had a counterfeit carton, counterfeit instructional insert, and counterfeit vial label.

48. On April 21, 2017, investigators from Exiger directed a pharmacy in the Eastern District of New York to place a phone order to H&H for two cases of FreeStyle test strips. On April 24, 2017, the pharmacist informed Exiger that the order of two cases had arrived. An investigator from Exiger retrieved the cases from the pharmacy on April 25, 2017. On May 3, Exiger sent ten of the twelve boxes in the second case to Erich Speckin, care of Speckin Forensics LLC ("Speckin") in Fort Lauderdale, Florida. Mr. Speckin found a number of significant differences in the packaging and instructional inserts between the suspected counterfeit product and the genuine product and concluded that the product sold by H&H was counterfeit.

49. On May 1, 2017, K2 Intelligence used a confidential entity in the Eastern District of New York to purchase product from H&H. This package contained twelve cases of FreeStyle test strips marked with lot number 1625010 and an expiration date of September 30, 2018. K2 Intelligence sent four boxes to Abbott and four boxes to Speckin. Both Abbott and Speckin determined that this package contained counterfeit boxes, counterfeit instructional inserts and counterfeit vial labels.

50. On May 11, 2017, Exiger used a pharmacy located in the Eastern District of New York to purchase product from H&H. Exiger received a package from H&H containing two cases of FreeStyle test strips marked with lot number 1625010 on May 16, 2017. Abbott determined by looking at true and correct pictures taken by Exiger of the product that this package contained counterfeit boxes, counterfeit instructional inserts and counterfeit vial labels.

51. By comparing the suspect products to the authentic product retained by Abbott, Abbott learned of numerous material differences in the labels and packaging, including differences in the size, spacing, boldness, color and appearance of the font graphics and artwork. These differences, along with the differences in the information assigned to the suspect vials, provided conclusive evidence that the labels and cartons were not manufactured by Abbott.

52. Moreover, critical information on the label, including expiration date, no longer corresponds to the test strips inside the vial, which come from a different lot number altogether. The FDA requires FreeStyle test strips to bear expiration dates based on the date of manufacture. Because the expiration date on the counterfeit packaging does not correspond to these strips, the strips may be expired, or will expire prior to the date on the counterfeit boxes. Beyond this, Abbott also does not know under what conditions the adulterated test strips were relabeled, shipped and stored and, therefore, Abbott cannot vouch for the quality, safety and integrity of the repackaged test strips. If the test strips were improperly handled, the repackaging alone might adversely affect their performance. Inaccurate or unreliable blood glucose readings present a possibility of harm to people with diabetes who depend on accurate readings to structure their food intake, make treatment decisions, and safely engage in daily activities.

53. In addition, the counterfeit packaging and vial labels no longer bear the authentic manufacturing lot codes for the strips inside the vial, which makes it impossible to perform a recall of the original lot numbers were that ever required.

Authorized Distribution of Genuine FreeStyle Test Strips in the United States

54. Authentic retail U.S. FreeStyle test strips are designed for sale by U.S. pharmacies. They can be sold to anyone in the United States, including customers covered by a prescription benefit and customers who would like to pay cash over-the-counter. Abbott wholesales retail boxes of FreeStyle test strips at a set list price throughout the United States.

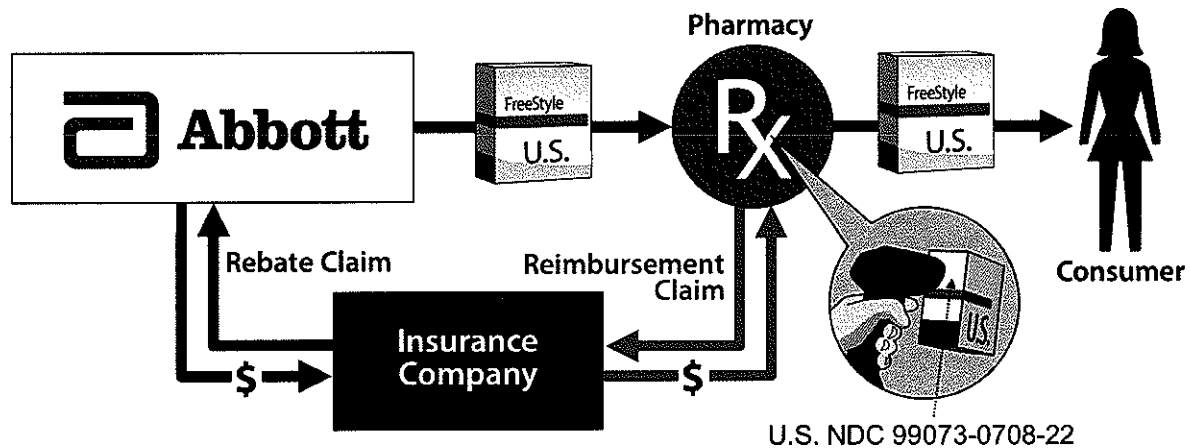
55. Abbott sells test strips outside of North America in international packaging, often in multiple languages. One or more repackagers is collecting FreeStyle test strips with international packaging, and breaking the seals on these international packaged cartons. The repackagers are then removing the vials that contain the test strips from the cartons and stripping the foreign-language labels off of the vials. The vials are then relabeled with counterfeit labels copied from genuine product sold in the United States and are then repackaged into counterfeit boxes that are copies of authentic boxes sold in the United States.

56. Most U.S. consumers—over 95%—purchase FreeStyle test strips with a prescription. Consumers with prescriptions for test strips are typically eligible to receive insurance coverage for their purchase, usually from private insurance or Medicare and Medicaid programs. Insurers provide prescription drug coverage according to a formulary, which is a schedule that lists the prescription drugs and medical devices the insurer will cover and the amount the insurer will reimburse for any particular drug or device. These formularies list the drugs and devices eligible for reimbursement according to the National Drug Code (“NDC”) number. If a product does not have an NDC number that is listed on the insurer’s formulary, it is not eligible for reimbursement from insurers.

57. When a pharmacy dispenses a box of FreeStyle test strips to a consumer who is using a prescription benefit, it informs the consumer's insurer of the purchase by scanning the unique U.S. FreeStyle test strips NDC number into the pharmacy computer terminal.

58. NDC numbers are used as a key component of reimbursement systems that enable automated processing of claims. The pharmacy scans the U.S. retail NDC number to submit a claim to the insurer for reimbursement. The insurance claim is processed according to the NDC number. The submission of the NDC number is a representation that the consumer was dispensed the product corresponding to the submitted NDC—that is, a box of FreeStyle test strips intended and authorized for sale in the United States. And based on this representation, the insurer makes a reimbursement payment to the pharmacy. This process is referred to as “adjudication.”

59. Insurers, third-party payers, and other large purchasers negotiate and contract with Abbott concerning how much they will pay—or more precisely, how much they will be rebated—for FreeStyle test strips. Pursuant to these contracts, when a transaction is adjudicated, Abbott also pays a rebate for every box of FreeStyle test strips for which an insurer paid or reimbursed the pharmacy. As the H&H Defendants are well aware, Abbott pays substantial rebates to the insurers for reimbursements they pay out on sales of U.S. FreeStyle test strips. Abbott's revenue for the sale of every adjudicated box of U.S. FreeStyle test strips therefore amounts to the list price minus the contractually agreed-upon rebate it pays to the insurer. The U.S. adjudication process, including reimbursement and rebate payment, is illustrated in **Figure 1**:



Legal Distribution Chain

Figure 1

60. Insurers who are covering test strips under a prescription benefit will not pay any reimbursement for the sale of FreeStyle test strips without a valid NDC number. And Abbott will not pay any rebate for the sale of FreeStyle test strips without a valid NDC number. It would be fraudulent for a distributor or retailer of FreeStyle test strips to utilize counterfeit retail U.S. packaging, which includes a U.S. NDC number, to pass off international FreeStyle test strips, which do not have a U.S. NDC number, as U.S. retail strips, and thereby secure the reimbursement paid by the insurers on a U.S. retail box of FreeStyle test strips. The same actions would amount to a fraud against Abbott, who would be paying rebates secured by the same counterfeit passing off. This is exactly what is happening here.

The Mechanics of Defendants' Illegal and Fraudulent Scheme

61. Defendants are participating in a scheme to defraud Abbott by purchasing international FreeStyle test strips, repackaging them into counterfeit packages with counterfeit instructional inserts and counterfeit vial labels, diverting those strips into the United States (whether before or after the repackaging) and selling them to U.S. consumers.

62. In many foreign countries, the list price for FreeStyle test strips is lower than in the United States. This is because the insurance systems in those countries differ from those in the United States. In particular, they involve little or no reimbursements or rebates. After all reimbursements and rebates are considered, the net price for U.S. and foreign FreeStyle test strips is similar throughout the developed world.

63. Because the list price for international FreeStyle test strips is lower than the U.S. list price, the H&H Defendants (and others like them) are buying large quantities of international FreeStyle test strips, diverting the test strips into the United States (whether before or after the repackaging), and selling them into the U.S. stream of commerce, knowing they will be sold to U.S. consumers with insurance. Retailers (in most cases, pharmacies) are then submitting these sales to insurers for reimbursement to obtain inflated profits.

64. To enable the retailers to receive these reimbursements, Defendants are engaging in fraudulent and criminal conduct. For nearly every sale of counterfeit FreeStyle test strips made to a U.S. consumer, retailers are dispensing the test strips pursuant to the consumer's prescription benefit. Although international FreeStyle test strips in their original, authentic packaging do not have an NDC number, the counterfeit packaging of the repackaged international test strips bears the NDC number of retail U.S. FreeStyle test strips, allowing retailers to improperly scan in the NDC code as though it were a retail box of U.S. FreeStyle test strips. Thus, while the retailers are dispensing diverted international FreeStyle test strips (which are ineligible for reimbursements and rebates in the United States), they fraudulently claim to have sold a box of U.S. FreeStyle test strips with a valid NDC number (which is eligible for reimbursements and rebates).

65. This fraud is first visited on U.S. consumers. By dispensing diverted international FreeStyle test strips in counterfeit packaging, Defendants are exposing each consumer to the threat posed by using adulterated, repackaged test strips that have been removed from the effective scope of Abbott's quality control procedures and that bear labelling that does not correspond to the test strips inside the vial. U.S. consumers see no savings and in fact pay the same amount for a box of diverted international test strips as they would for a box of U.S. FreeStyle test strips. So for the same price, these consumers are receiving a box of FreeStyle test strips that are counterfeit, adulterated, and pose a potential health and safety risk.

66. For each of these sales Defendants have made and continue to make, they are knowingly causing a false claim for reimbursement to be submitted with the consumer's insurer. Based on the falsely adjudicated NDC number from the counterfeit packaging, insurance companies have paid out and continue to pay out reimbursements to retailers of the counterfeit test strips.

67. These fraudulent adjudications are then forwarded on to Abbott. Just as insurance companies do not provide reimbursements for products without an NDC number, Abbott does not provide rebates to insurers unless the pharmacies provide the NDC number of a rebate-eligible product they claim to have dispensed. For every reimbursement wrongfully paid by an insurer based on a fraudulent NDC number set forth on counterfeit packaging, the insurer then submits a claim for a rebate from Abbott pursuant to their agreed-upon rebate structure. And as Defendants know, as it is fundamental to their scheme, it is then Abbott that pays the rebate to the insurer based on the same fraudulent counterfeit NDC number caused to be transmitted by Defendants.

68. Abbott has suffered and continues to suffer significant losses at the hand of the H&H Defendants' fraudulent scheme. For each sale of international FreeStyle test strips in counterfeit U.S. packaging for which Abbott pays a rebate, Abbott first receives the foreign list price, which is significantly lower than the U.S. list price. Then, Abbott pays a rebate that it is not supposed to pay. Thus, each of these transactions results in a net loss for Abbott.

69. Abbott's financial loss is Defendants' gain. Because over 95% of U.S. consumers purchase FreeStyle test strips with a prescription and insurance, there is minimal return—and thus minimal incentive—for retailers to sell international FreeStyle test strips in counterfeit U.S. packaging over-the-counter for cash.

70. Repackaging international FreeStyle test strips into counterfeit packaging is very profitable for Defendants, though, precisely because retailers fraudulently submit their sales directly for reimbursements and indirectly for rebates. This is the central purpose of Defendants' conspiracy.

Defendants' Prior Fraudulent and Criminal Acts

71. This is not the first time H&H has been involved in the unauthorized sale of blood glucose test strips. H&H is a recidivist when it comes to the unlawful sale and distribution of diverted and/or counterfeit test strips.

72. As described above, Abbott sued H&H and Howard Goldman, among other defendants, in the Related Action. The Preliminary Injunction entered against H&H and Howard Goldman in the Related Action is in effect as of the date of this Complaint. H&H's purchase and sale of international FreeStyle test strips that have been repackaged into counterfeit U.S. retail packaging and labelling is a flagrant subversion of that Preliminary Injunction.

73. H&H has also been the subject of a series of government seizures, warning letters, and enforcement actions dating as far back as 2005 concerning its purchase and sale of non-FDA approved blood glucose test strips and related medical devices. As recently as 2012, the FDA warned H&H that its practices for purchasing, storing and selling glucose test strips were in violation of federal regulations. *See* Warning Letter 2012-DET-09, U.S. Food & Drug Administration (March 27, 2012), *available* at www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm297885.htm.

74. H&H has also been the subject of at least two other civil suits brought by other blood glucose strip manufacturers relating to its bad conduct.

75. In 2009, H&H and its principal agent, defendant Howard Goldman, were among several defendants sued by Johnson & Johnson and LifeScan in connection with the manufacture and distribution of counterfeit OneTouch test strips. *See* Sixth Amended Complaint, *Johnson & Johnson et al. v. South Pointe Wholesale, Inc., et al.*, No. 08-civ-1297, Dkt. No. 265 (E.D.N.Y. May 21, 2009). In that case, H&H acknowledged that it purchased more than 20,000 boxes of LifeScan test strips from abroad, and Chief Magistrate Judge Gold concluded that all of those boxes were counterfeit. Report & Recommendation, *South Pointe Wholesale, Inc.*, No. 08-civ-1297, Dkt. No. 769 at 18, 40-41 (E.D.N.Y. Mar. 28, 2014).

76. LifeScan sued H&H again in 2014, this time in Massachusetts federal court, making allegations similar to those that Abbott makes here: that H&H's sale of diverted international test strips within the United States was illegal. Complaint, *Johnson & Johnson v. H&H Wholesale Services, Inc.*, No. 1:14-cv-10346, Dkt. No. 1 (D. Mass. Feb. 18, 2014). LifeScan and H&H settled the New York counterfeiting case and the Massachusetts illegal diversion case, with H&H paying LifeScan \$2 million. Consent Judgment and Permanent

Injunction at 1, *LifeScan v. South Pointe Wholesale, Inc., et al.*, No. 08-civ-1297, Dkt. No. 816 (E.D.N.Y. Nov. 25, 2014). The judgment signed by Judge Townes permanently enjoined H&H from selling diverted international LifeScan test strips. *Id.* After this settlement, LifeScan agreed to dismiss its Massachusetts lawsuit against H&H. Stipulation of Dismissal, *Johnson & Johnson v. H&H Wholesale Services, Inc.*, No. 1:14-cv-10346, Dkt. No. 40 (D. Mass. Dec. 4, 2014).

77. The H&H Defendants' conduct continues to date. Defendants' conspiracy continues to mislead and confuse consumers; continues to subject consumers to adulterated, counterfeit test strips that have been taken outside of Abbott's quality control measures; continues to defraud third-party payers; and continues to cause irreparable and monetary harm to Abbott.

78. In short, the H&H Defendants are fully engaged in the illegitimate business of selling counterfeit FreeStyle test strips worldwide, availing themselves repeatedly of the United States, and New York in particular, as a forum to which their counterfeit products can be shipped, from which those products can be sold, and through which U.S. dollars can be sent and received.

79. Plaintiffs have no adequate remedy at law to prevent defendants' wrongful conduct.

FIRST CAUSE OF ACTION
FEDERAL TRADEMARK INFRINGEMENT

80. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

81. In violation of 15 U.S.C. § 1114(1)(a), Defendants, independently and in conspiracy with one another, used in commerce, without Abbott's consent, either a reproduction, counterfeit, copy or colorable imitation of the FreeStyle Marks in connection

with the sale, offering for sale, distribution, or advertising of counterfeit packaged FreeStyle test strips or in connection with which such use that is likely to cause confusion, or to cause mistake or to deceive.

**SECOND CAUSE OF ACTION:
FEDERAL TRADEMARK INFRINGEMENT**

82. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

83. In violation of 15 U.S.C. § 1114(1)(b), Defendants, independently and in conspiracy with one another, reproduced, counterfeited, copied or colorably imitated a registered mark, slogan and/or trade dress belonging to Abbott and applied such reproduction, counterfeit, copy or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the offering for sale, distribution or advertising of counterfeit packaged FreeStyle test strips on or in connection with such use that is likely to cause confusion, to cause mistake or to deceive.

**THIRD CAUSE OF ACTION:
FALSE DESCRIPTION AND DESIGNATION OF ORIGIN IN COMMERCE**

84. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

85. In violation of 15 U.S.C. § 1125(a)(1)(A), Defendants, independently and in conspiracy with one another, in connection with the counterfeit Abbott products, used in commerce a slogan, trade dress, word, term, name, symbol or device, or any combination thereof, or a false designation of origin, false or misleading description of fact or false or misleading representation of fact, which was or is likely to cause confusion or to cause mistake, or to deceive as to an affiliation, connection, or association with Abbott.

**FOURTH CAUSE OF ACTION:
FEDERAL FALSE ADVERTISING**

86. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

87. In violation of 15 U.S.C. § 1125(a)(1)(B), Defendants, independently and in conspiracy with one another, in connection with the sale of the counterfeit Abbott products, used a slogan, trade dress, word, term, name, symbol, or device or any combination thereof, or a false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, and qualities of the counterfeit Abbott products.

**FIFTH CAUSE OF ACTION:
FEDERAL DILUTION OF MARK**

88. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

89. The FreeStyle Marks are famous and distinctive within the meaning of 15 U.S.C. § 1125(c).

90. Defendants are selling and/or have sold counterfeit products bearing the FreeStyle Marks after such trademarks and trade dress became famous.

91. By selling these counterfeit packaged products, Defendants, independently and in conspiracy with one another, have diluted and are diluting the distinctive quality of a mark or trade name owned by Abbott in violation of 15 U.S.C. § 1125(c).

**SIXTH CAUSE OF ACTION:
NEW YORK DILUTION OF MARK AND INJURY TO BUSINESS REPUTATION**

92. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

93. The FreeStyle Marks are distinctive within the meaning of New York General Business Law § 360-1.

94. By selling counterfeit products bearing the FreeStyle Marks, Defendants, independently and in conspiracy with one another, have injured and are continuing to injure Abbott's business reputation and/or have diluted and are continuing to dilute the distinctive quality of a mark or trade name owned by Abbott, in violation of New York General Business Law § 360-1.

**SEVENTH CAUSE OF ACTION
NEW YORK DECEPTIVE BUSINESS PRACTICES**

95. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

96. In violation of New York General Business Law § 349, Defendants, independently and in conspiracy with one another, are selling, offering for sale and/or distributing low quality counterfeit products unlawfully bearing the FreeStyle Marks.

**EIGHTH CAUSE OF ACTION:
COMMON LAW UNFAIR COMPETITION**

97. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

98. In violation of the common law of the State of New York and elsewhere, the defendants, independently and in conspiracy with one another, have unfairly competed with Abbott by selling the counterfeit products.

**NINTH CAUSE OF ACTION:
COMMON LAW UNJUST ENRICHMENT**

99. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

100. By selling the counterfeit products bearing Abbott's valuable trademarks independently and in conspiracy with one another, Defendants have been unjustly enriched at Plaintiffs' expense in violation of the common law of New York and elsewhere.

**TENTH CAUSE OF ACTION:
COMMON LAW FRAUD AND FRAUDULENT INDUCEMENT**

101. Plaintiffs incorporate each paragraph of this Complaint as if fully set forth herein.

102. Defendants (including the John Doe defendants) intentionally made or caused to be made knowingly false representations to Abbott and insurers, and intentionally omitted material facts from Abbott and insurers.

103. Namely, H&H intentionally misrepresented to its customers, including pharmacies and nursing homes, that they were being sold authentic U.S. retail FreeStyle test strips when, in fact, they dispensed international FreeStyle test strips in counterfeit packaging. Defendants knew these misrepresentations were passed to insurers when the counterfeit FreeStyle strips were sold by the John Doe defendants, and that those misrepresentations were inadvertently passed along by the insurers, which in turn caused Abbott to pay the insurers rebates.

104. Defendants never informed Abbott or the insurers, that they have been selling diverted international test strips in counterfeit packaging, or that they had sold product with false and counterfeit NDC numbers knowing they would be used in insurance reimbursement claims, or that they had submitted false and counterfeit NDC numbers to insurers that they knew would be inadvertently passed by the insurers to Abbott.

105. Defendants made or caused to be made these false representations and material omissions with the intent of defrauding Abbott.

106. Defendants knew and intended that Abbott would rely on their false representations and material omissions and, as a result, would incorrectly pay rebates.

107. Had Abbott known the true facts regarding Defendants' fraud, it would not have paid rebates to the insurers for the diverted international test strips.

108. As a result of Defendants' conduct, Abbott has suffered significant injury.

**ELEVENTH CAUSE OF ACTION:
COMMON LAW AIDING AND ABETTING FRAUD**

109. Abbott incorporates each paragraph of this Complaint as if fully set forth herein.

110. Each Defendant (including the John Doe defendants) intentionally provided substantial assistance to the others in advancing the fraud against Abbott.

111. Each Defendant intentionally provided substantial assistance to the others in advancing the fraud against Abbott.

112. Each Defendant either directed a pharmacy or nursing home (including without limitation a John Doe defendant) or endorsed the direction of a pharmacy or nursing home (including without limitation a John Doe defendant) to fraudulently adjudicate the sale of international FreeStyle test strips in counterfeit U.S. retail packaging as a sale of authentic U.S. retail FreeStyle test strips in order to profit from the higher reimbursements and rebates associated with the latter.

113. All Defendants knowingly hid the fraud from Abbott, by omitting to inform Abbott of the fraud.

114. Defendants could not have perpetrated and expanded their fraud without the substantial and material assistance of each other Defendant. Each Defendant benefited from the success of the fraud.

115. All Defendants had actual knowledge of, and substantially assisted in, the fraudulent scheme.

116. As a result of Defendants' conduct, Abbott has suffered significant injury.

RELIEF SOUGHT

WHEREFORE, Plaintiffs demand judgment against the defendants as follows:

(a) that a temporary restraining order and preliminary and permanent injunctions be issued enjoining each and every one of the defendants and their subsidiaries, parents, affiliates, agents, servants, employees, members, directors, officers and attorneys and those persons in active concert or participation with them:

- (i) from using any of the FreeStyle Marks, whether genuine or counterfeit, or any marks confusingly similar thereto in connection with the manufacture, sale, offer for sale, distribution, advertisement, or any other use of blood glucose test strips;
- (ii) from using any logo, trade name or trademark confusingly similar to any of the FreeStyle Marks which may be calculated to falsely represent or which has the effect of falsely representing that the services or products of the defendants or of others are sponsored by, authorized by or in any way associated with Plaintiffs;
- (iii) from infringing any of the FreeStyle Marks;
- (iv) from otherwise unfairly competing with Abbott in the manufacture, sale, offering for sale, distribution, advertisement, or any other use of FreeStyle test strips;
- (v) from falsely representing themselves as being connected with Plaintiffs or sponsored by or associated with Plaintiffs or engaging in any act which is likely to cause the trade, retailers and/or members of the purchasing public to believe that defendant is associated with Plaintiffs;

- (vi) from using any reproduction, counterfeit, copy, or colorable imitation of any of the FreeStyle Marks in connection with the publicity, promotion, sale, or advertising of blood glucose test strips;
- (vii) from affixing, applying, annexing or using in connection with the sale of any goods, a false description or representation including words or other symbols tending to falsely describe or represent such goods as being FreeStyle test strips and from offering such goods in commerce;
- (viii) from diluting any of the FreeStyle Marks;
- (ix) from destroying any records documenting the manufacture, sale, offer for sale, distribution, advertisement or receipt of any product purporting to be FreeStyle test strips; and
- (x) from assisting, aiding or abetting any other person or business entity in engaging in or performing any of the activities referred to in subparagraphs (i) through (ix) above; and

(b) ordering that, within fifteen days after the entry and service of a temporary, preliminary or permanent injunction, the defendants serve and file a written report under oath setting forth in detail the manner and form in which they have complied with the injunction; and

(c) ordering that all infringing material be turned over, seized, impounded and/or destroyed; and

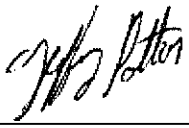
(d) awarding to Plaintiffs punitive damages from each defendant in an amount to be ascertained at trial, but in no event less than \$25 million; and

(e) awarding to Plaintiffs statutory and actual damages and costs in an amount to be ascertained at trial, and costs and attorney's fees; and

- (f) awarding to Plaintiffs an accounting, and an award of: (i) all ill-gotten profits from the defendants' manufacture, sale and/or distribution of the counterfeit FreeStyle test strips; (ii) Plaintiffs' lost profits; and (iii) Plaintiffs' remedial costs; and
- (g) awarding to Plaintiffs pre-judgment and post-judgment interest; and
- (h) awarding such other and further relief to Plaintiffs as may be just and proper.

DATED: May 23, 2017
New York, New York

By: _____


Geoffrey Potter
gpotter@pbwt.com

PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
Tel: (212) 336-2000
Fax: (212) 336-2222

*Attorneys for Plaintiffs Abbott Laboratories, Abbott
Diabetes Care Inc., and Abbott Diabetes Care Sales
Corporation*